



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,197	01/18/2002	Juan Carlos Parodi	BSI-473US	8674

7590

01/13/2004

RATNER & PRESTIA

Suite 301

One Westlakes, Berwyn

P.O. Box 980

Valley Forge, PA 19482-0980

EXAMINER

PANTUCK, BRADFORD C

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,197

Applicant(s)

PARODI, JUAN CARLOS

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 12, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, and 8-35 is/are rejected.
- 7) ☒ Claim(s) 4 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 5. 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 10 is objected to because of the following informalities: in line 7, *lumen* should be changed to *lumens*. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-13 and 25-34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 8 recites the limitation "the prosthesis" in line 1. There is insufficient antecedent basis for this limitation in the claim.
3. Claim 25 recites the limitation "the lumen" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 30 recites the limitation "the proximal stent portion" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. This phrase is vague because the stent has different proximal and distal portions because it has a trunk portion and arm portions. If Applicant means the "proximal trunk stent portion," then Applicant should use the appropriate language.
5. Claim 32 recites the limitation "the lumen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 3731

6. Claim 34 recites the limitation "the anchor balloon" in step (d) line 1. There is insufficient antecedent basis for this limitation in the claim.
7. Regarding Claim 33, Applicant claimed two different introducers with different components (the second has a peripheral guide channel, the first does not). Further limiting the invention by saying these two introducers are the same is unclear and does not make sense.
8. Regarding Claim 34, Applicant should name either the "peripheral guide wire" or the "axial guide wire," rather than using the generic term "wire" in step (c) line 3.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,616,679 to Khosravi et al. Regarding Claims 1 and 2, Khosravi discloses an introducer for insertion into an artery. The introducer has an outer sheath (95), an axial guide wire (71) slidable inside the sheath, and a peripheral guide wire (80) also slidable inside the outer sheath [Figures 8A & 8B]. Khosravi also discloses a nose cone (76) having an axial (i.e., directed parallel to the longitudinal axis of the

Art Unit: 3731

sheath) conduit (74) slidable over the axial guide wire. The nose cone (76) has another peripheral channel (79) spaced apart from the axial conduit for receiving another guide wire (80). This peripheral (i.e., located close to the periphery of the sheath) channel (79) is open to the outside edge of the nose cone [Column 8, lines 34-48].

10. Regarding Claim 3, the peripheral channel (79) provides communication between the inside of the sheath (95) and the outside environment [apparent from Fig. 8A].

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-3, 5, 6, and 14-23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,524,335 to Hartley et al. Regarding Claims 1, 2, 5, 14-16, and 18-20 Hartley discloses an introducer for insertion into an artery. The introducer has an outer sheath (26), an axial guide wire (22) slidable inside the sheath, and peripheral guide wires (40 & 42) also slidable inside the outer sheath [Figure 8]. Hartley also discloses a nose cone [or “prosthesis”] (5) having an axial (i.e., directed

parallel to the longitudinal axis of the sheath) conduit (inside lumen) slidable over the axial guide wire. The nose cone (5) has two peripheral channels (10) spaced apart from the axial conduit for receiving guide wires (40 & 42) [Column 4, lines 53-60]. The peripheral (i.e., located close to the periphery of the sheath) channels (10) are open to the outside edge of the nose cone [Figures 8 and 9]. A *channel*, as used in the context of the claims, is considered to be a tubular passage, and channels (10) meet this definition, as each has length, height, and width. The channels, which extend perpendicular to the trunk, are particularly obvious in Figure 9.

12. Regarding Claim 3, the peripheral channels (10) provide communication between the inside of the sheath (26) and the outside environment, *when the nose cone (5) is positioned at the distal end of the sheath* [as very nearly shown in Fig. 7].
13. Regarding Claim 6 and 17, the two peripheral channels (10) are located at diametrically opposed locations on the nose cone (5) [Fig. 7; Column 5, lines 57-61].
14. Regarding Claim 21, Hartley's unitary prosthesis is adapted to be deployed at the junction of the aorta and the renal arteries [Column 4, lines 32-38; Figure 8].
15. Regarding Claim 22, Hartley's prosthesis (5/7/8) includes a graft (7) and a stent (5) [Column 4, lines 42-49; Figure 2]. The word "graft" refers to something (anything) that can be implanted in the body. The word "stent" refers to a tubular structure, which can support a body lumen.
16. Regarding Claim 23, Hartley's stent (5) has a trunk portion and two branch segments, all of which are expandable from the state shown in Figure 8 to that of Figure 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,524,335 to Hartley et al. Hartley discloses the prosthesis of claim 23, but fails to disclose each portion being a separate stent. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to form the trunk segments and the branch segments as separate stents, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Allowable Subject Matter

18. Claims 4 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,283,951 to Flaherty et al. [see Fig. 6]

U.S. Patent No. 6,458,098 B1 to Kanesaka [see Fig. 5]

Art Unit: 3731

U.S. Patent No. 5,713,363 to Seward et al.

U.S. Patent No. 6,129,738 to Lashinski et al.

U.S. Patent No. 6,053,911 to Ryan et al.

U.S. Patent No. 6,589,251 B2 to Yee et al. [Fig. 15]

U.S. Patent No. 6,652,569 B1 to Taylor et al.

U.S. Patent No. 4,921,383 to Wijay et al.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621.

The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
BCP
January 7, 2004


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700